5/7/01

K003403 510(k) SUMMARY

The Summary of Safety and Effectiveness on the Endoscopic Monopolar Electrodes reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant	John Niksa, President Highland / Marietta, Inc. 6155 Heisley Road Mentor, Ohio 44060
Telephone	440/354-0957
Facsimile	440/354-6106
Date	May 4, 2001
Name	Endoscopic Monopolar Electrodes
Classification	Endoscopic, unipolar, coagulator-cutter, 21 CFR 884.4160
Predicate:	Gynescope Electrodes, 510(k) K902658/A
Description	The design description of the Family of Endoscopic Electrodes are intended for use in general or gynecologic surgical procedures that utilize minimally invasive surgical procedures to provide monopolar electrocautery capability to dissect and coagulate tissue. The availability of a variety of proximal tip configurations is to accommodate the different needs during electro surgical procedures: Electrode with luer: Hook Sling Right Angle Knife Spatula Electrode without luer: Cone Button The devices (Hook; Sling; Right Angle; Knife; and Spatula) consist of an insulated stainless steel tube with a tip configuration at the distal end; a monopolar post at the proximal end for connection to the electro surgical generator; and a luer for the purpose of flushing and irrigation. The luer can be manually turn to control the flow of the fluid during the surgical use for the purpose of irrigation / suction; and during the cleaning / sterilization of the electrode. The Cone and Button electrodes consist of an insulated stainless steel tube with a tip configuration at the distal end; a monopolar post at the proximal end for connection to the electro surgical generator; and they do not have a luer connection, as the end of the shaft at the distal end is a solid.
Intended Use	The Family of Endoscopic Electrodes are reusable devices intended for use in general or gynecologic surgical procedures that utilize minimally invasive surgical procedures to provide monopolar electrocautery capability to dissect and coagulate tissue.
Warning:	Do not use any instrument that exhibits insulation degradation. Any damage of the insulation such as dents, scratches, cracking or splitting may allow electric current leakage and cause shock to the patient or doctor.

K003403 510(k) SUMMARY continue

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Warning continue:	Keep voltage/power as low as possible to achieve the desired effect, maximum power should not exceed 120 watts. Please refer to the electro surgical generator and laparoscope labeling for contraindications and any additional warnings or precautions. Co activating electrical stimulus with aspiration/ irrigation may incur gap coupling through shaft area and arcing at distal end.
Caution:	Federal law (U.S.A.) restricts this device to sale by or on the order of a physician. Do not activate the electro surgical unit simultaneously with the aspiration / irrigation mode as this condition may alter the path of the electrical energy away from the target tissue.
Precaution:	The user should use cautions to ensure that all minimally invasive components including laparoscope, forceps, trocars and sleeves, electrocautery units, cables, and patient grounding plate are compatible and intended for minimally invasive surgery. It is critical that all intended electro surgical instruments be in contact with or next to the tissue or target prior to activation of the generator to eliminate the possibility of voltage/current seeking an exit through the insulation to the closet "ground". Activate generator only when instrument is in position.
Technological Characteristics	The intended use and technological characteristics of these devices do not vary significantly. The safety and effectiveness of the Endoscopic Monopolar Electrodes are comparable to that of the Gynescope Monopolar Electrodes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2001

Mr. John Niksa
President
Highland / Marietta, Inc.
6155 Heisley Road
MENTOR OH 44060

Re: K003403
Endoscopic Monopolar Electrodes with hook, sling, knife, spatula, right angle, cone, and button tips
Dated: February 27, 2001
Received: February 27, 2001
Regulatory Class: II
21 CFR §878.4400/Procode: 79 JOS
21 CFR §884.4160/Procode: 85 KNF

Dear Mr. Niksa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003403

Device Name: Endoscopic Monopolar Electodes

Indications For Use:

The Family of Endoscopic Electrodes are reusable devices intended for use in general or gynecologic surgical procedures that utilize minimally invasive surgical procedures to provide monopolar electrocautery capability to dissect and coagulate tissue.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003403

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)